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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,114	07/16/2001	Huanmin Zhang	210707US20	3555

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1636	8

DATE MAILED: 09/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,114	ZHANG ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-56 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

I. Claims 1-7 and 9-16, drawn to an isolated polynucleotide sequence comprising SEQ ID NO:1 or SEQ ID NO:3 or an isolated polynucleotide which hybridizes under stringent conditions to the same polynucleotide sequence, a vector, a host cell comprising the same isolated polynucleotide sequence, and a method for producing a fertility associated antigen by introducing an isolated polynucleotide encoding fertility associated antigen into a host cell, classified in class 536, subclass 23.5; class 435, subclasses 320.1, 69.1, for examples.

II. Claims 8 and 17-54, drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:2 and methods of increasing the stability of the plasma membrane plus acrosome of a sperm cell and/or other portions of a sperm cell, of increasing fertility of sperm from a mammal or an avian, or of increasing the fertility of a male mammal using a fertility associated antigen having SEQ ID NO:2 or a recombinantly produced fertility associated antigen, classified in class 530, subclass 350; class 514, subclass 2, for examples.

III. Claims 55-56, drawn to a transgenic non-human mammal or avian comprising and expressing the isolated polynucleotide sequence comprising SEQ ID NO:1 or SEQ ID NO:2, classified in class 800, subclasses 8, 14, 19, for examples.

Should Applicants elect the invention of Group II, further group restriction is required. Claims 17 and 24 link a plurality of patentably distinct groups of mammalian and avian sperm cells that lack the unity of invention because they do not share a substantial common core structure or element among themselves. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect either mammalian sperm cells or avian sperm cells.

Should Applicants elect the invention of Group III, further group restriction is required. Claim 55 link a plurality of patentably distinct groups of transgenic non-human mammal and transgenic avian expressing the isolated polynucleotide sequence of the presently claimed invention, that lack the unity of invention because they do not share a substantial common core structure or element among themselves (a non-human mammal versus an avian). As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect either transgenic non-human mammal or transgenic avian.

The restriction requirement between linked inventions is subject to the non-allowance of the linking claims 17, 24 and 55. The restriction requirement between linked inventions is subject to the non-allowance of the linking claim(s), 17, 24 and 55.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are distinct each from the others as they are drawn to distinct compositions such as an isolated polynucleotide sequence encoding a fertility associated antigen of Group I, an isolated polypeptide encoding a fertility associated antigen having SEQ ID NO:2 of Group II, and a transgenic non-human mammal or avian comprising and expressing an isolated polynucleotide encoding a fertility associated antigen of Group III. The isolated polynucleotide of Group I is made up of nucleotides, whereas the isolated polypeptide of Group II is composed of amino

acid residues, and the transgenic non-human mammal or avian of Group III is a living animal which is not required for any of the methods including in Groups I and II. Additionally, the recombinant fertility associated antigen produced by the method in Group I can be used to generate antibodies specific against fertility associated antigen for purification purposes, and it is not necessarily limited to be utilized in the methods of Group II.

Because these inventions are distinct for the reasons set forth above, it would be unduly burdensome for the examiner to search and/or consider the patentability of all of the inventions in a single patent application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect the invention of Group II, and mammalian sperm cell as a separate group, the invention contains claims 17-19, 22-26, 29-38, 47-52 which are generic to a plurality of disclosed distinct species comprising:

(i) buffalo; (ii) cattle or cow; (iii) horses; (iv) humans; (v) mice; (vi) pigs; and (vi) sheep.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect the invention of Group II, and avian sperm cell as a separate group, the invention contains claims 17, 20-24, 27-30, 39-46 which are generic to a plurality of disclosed distinct species comprising:

(i) a chicken; and (ii) a turkey.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect the invention of Group III, and a transgenic non-human mammal as a separate group, the invention contains claims 55-56 which is generic to a plurality of disclosed distinct species comprising:

(i) a cow; (ii) a goat; (iii) a pig; and (iv) a sheep.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER